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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,087	02/11/2002	Chung-Fan Chiou	32350-178362	1547

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EXAMINER
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FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/071,087

**Applicant(s)**

CHIOU ET AL.

**Examiner**

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group II, Claims 41-54 in papers filed 14 May 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 41-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 41-54 are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps for detecting nucleic acids. The claims are drawn to a method for detecting nucleic acid. However, the claims do not recited method steps of nucleic acid detection. Therefore, the claims are incomplete for omitting the essential step of nucleic acid detection.

b. Claim 42 is indefinite because the claim is drawn to differing methods of labeling i.e. fluorescence, chemiluminescence, electric signal and radioactive. However, the different

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labeling methods are recited in the inclusive "and" instead of the alternative "or". But it is unclear how all of the labeling methods are used in a single method of detection. It is suggested that Claim 42 be amended to clarify.

c. Claims 47 and 48 are each indefinite for the recitation "capable of paring with DNA (RNA)" because it is unclear whether the recitation is intended to describe hybridization or some other undefined paring. It is suggested that Claims 47 and 48 be amended to clarify.

d. Claim 53 is indefinite for the recitation "the oligonucleotides....are evenly distributed across the unique addressable area" because it is unclear whether the recitation is a method step of distributing or whether the recitation is intended to describe oligonucleotide positions on the area. It is suggested that Claim 53 be amended to clarify.

e. Claim 54 is indefinite for the recitation "the quantity of teach type of the oligonucleotide corresponds to it affinity to the target sequence" because "corresponds" is a non-specific relational term. Therefore, the relationship between the oligonucleotide and the sequence is undefined. It is suggested that Claim 54 be amended to define the relationship.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 41-52 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Gentalen et al (U.S. Patent No. 6,306,743, filed 24 August 1998).

Regarding Claim 41, Gentalen et al disclose a method for detecting nucleic acids comprising providing at least one probe set comprising multiple types of oligonucleotides (i.e. probe pools), providing a solid support having at least one unique addressable area, attaching the probe set to the addressable area, allowing sample nucleic acids to hybridize with probe sets, labeling the sample nucleic acids before hybridization and determining the results of hybridization (Column 2, lines 27-67; Column 3, line 62-Column 4, line 38; and Column 11, lines 1-11).

Regarding Claim 42, Gentalen et al disclose the method wherein the labeling is achieved by fluorescence labeling or chemiluminescence labeling (Column 11, lines 1-11).

Regarding Claim 43, Gentalen et al disclose the method wherein each probe set comprises 2 to 20 types of oligonucleotides having different sequences and each type of oligonucleotide specific to a different target sequence (i.e. different polymorphic form, Column 9, lines 38-57).

Regarding Claim 44, Gentalen et al disclose the method wherein each probe set comprises 2 to 4 types of oligonucleotides having different sequences and each type of oligonucleotide specific to a different target sequence (i.e. different polymorphic form, Column 9, lines 38-57).

Regarding Claim 45, Gentalen et al disclose the method wherein the length of each oligonucleotide is 4 to 400 bases (Column 6, lines 46-48 and Column 18, lines 21-30).

Regarding Claim 46, Gentalen et al disclose the method wherein the length of each oligonucleotide is 8 to 80 bases (Column 6, lines 46-48 and Column 18, lines 21-30).

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Regarding Claim 47, Gentalen et al disclose the method wherein the oligonucleotides are capable of paring with DNA i.e. the target is DNA (Column 10, lines 18-22 and Column 18, lines 13-49).

Regarding Claim 48, Gentalen et al disclose the method wherein the oligonucleotides are capable of paring with RNA i.e. the target is RNA (Column 10, lines 18-22 and Column 14, lines 4-44).

Regarding Claim 49, Gentalen et al disclose the method wherein the oligonucleotides are DNA (Column 6, lines 49-55).

Regarding Claim 50, Gentalen et al disclose the method wherein the oligonucleotides are RNA i.e. the oligonucleotide probes are single stranded nucleic acids which is a ribonucleotide (Column 6, lines 42-48).

Regarding Claim 51, Gentalen et al disclose the method wherein the oligonucleotides are PNAs (Column 6, lines 49-60).

Regarding Claim 52, Gentalen et al disclose the method wherein each probe set contains substantially equal quantities of each type of oligonucleotide (Column 11, lines 29-30).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gentalen et al (U.S. Patent No. 6,306,643, filed 24 August 1998) in view of Pease et al (Proc. Natl. Acad. Sci. USA, 1994, 91: 5022-5026).

Regarding Claim 53, Gentalen et al teach the method for detecting nucleic acids comprising providing at least one probe set comprising multiple types of oligonucleotides (i.e. probe pools), providing a solid support having at least one unique addressable area, attaching the probe set to the addressable area, allowing sample nucleic acids to hybridize with probe sets, labeling the sample nucleic acids before hybridization and determining the results of hybridization (Column 2, lines 27-67; Column 3, line 62-Column 4, line 38; and Column 11, lines 1-11) wherein the oligonucleotides are synthesized using the method of Pease et al (Column 17, lines 24-25). Pease et al teach their method wherein following deprotection of an addressable area, a monomer solution is flowed across the support to bind the monomer to the deprotected area (page 5023 and Fig. 1). This clearly suggests that the oligonucleotides of Gentalen et al are distributed evenly across the area because the area is evenly deprotected according to the method of Pease et al. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

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8. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gentalen et al (U.S. Patent No. 6,306,643, filed 24 August 1998) in view of Chenchik et al (U.S. Patent No. 6,489,159 filed 29 September 2000).

Regarding Claim 54, Gentalen et al teach the method for detecting nucleic acids comprising providing at least one probe set comprising multiple types of oligonucleotides (i.e. probe pools), providing a solid support having at least one unique addressable area, attaching the probe set to the addressable area, allowing sample nucleic acids to hybridize with probe sets, labeling the sample nucleic acids before hybridization and determining the results of hybridization (Column 2, lines 27-67; Column 3, line 62-Column 4, line 38; and Column 11, lines 1-11) wherein the quantity of each type of oligonucleotide may be varied (Column 3, lines 5-14) but they do not specifically teach the quantity corresponds to its affinity to the target sequence. However, probe quantity corresponding to target affinity was well known in the art at the time the claimed invention was made as taught by Chenchik et al. (Claim 7). Chenchik et al teach that quantity of each oligonucleotide is normalized to thereby provide a control support to which test supports are compared (Column 7, line 49-column 8, line 28). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the support of Gentalen et al by providing normalized quantities of each type of probe to the support to thereby provide a control support to which test samples are compared as desired by Chenchik et al (Column 7, line 49-column 8, line 28).



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**Conclusion**

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1634  
June 18, 2003